

REMARKS

1. Presently claims 1, 2, 4, 9 to 10, 12, and 15 are under examination. In amending claim 1, claim 15 became marginally different from the combination of claim 1 and claim 4, and is thus now cancelled.

2. The Examiner has rejected claims 1, 2, 4, 12 and 15 under 35 U.S.C. §103(a) as being unpatentable over Wolff ('554) for the reasons noted in paragraph 2 and over Whitehurst ('866) for reasons noted in paragraph 3.

The Examiner notes that Wolff discloses the use of electromagnetic radiation for the treatment of acne, psoriasis, etc. (Col. 1, lines 49-57)

Wolff minimally discloses, as unreferenced prior art, the treatment of the body for psoriasis, acne and other skin irregularities or diseases with UVA radiation in the range from about 315 to 400 nm. Col. 1, lines 20 to 28, and 50 to 55 being in the Background. As to the treatment of psoriasis and acne, Wolff notes that the prior apparatus filtered out radiation in the range of 300 to 315 nm "but that this is most effective for these purposes." Col. 1, lines 53 to 57. His main emphasis is an apparatus which can irradiate modest section of a person's body with wavelengths between 300 nm and 315 nm. (abstract, figures)

The Examiner states near the start of paragraph 2, that Wolff by disclosing wavelengths within the broader range described in the present invention (page 6, 4ff) from a non-coherent source makes obvious the present invention as claimed.

The amended claim 1, similar to the previous claim 15, does not claim the broad spectrum from ultraviolet into the mid infrared, but rather restricts itself to the wavelength region around the examples, namely 980 nm. These types of lasers have been used in the medical field since before 1995 to ablate, cauterize soft body tissue employing power levels ranging from a couple of Watts to 10-25 Watts. Use of coherent laser light as alluded to by Wolff, by Whitehurst (US 6,461,866) and other prior art (see prior listing present application), is most often to cut, ablate, and seal/weld body tissue in this power range. What is surprising then is that using a wavelength known in the art to be around the second harmonic of the O-H stretch (about 980 nm) could be used effectively in a non-ablative regime to speed up the healing of minor 'wounds' including spider bites, poison ivy reactions, etc. Since body tissue is

primarily water, the second harmonic of O-H stretch is a wavelength range that is significantly absorbed by such tissue, which commonly would have been thought to be a detriment to a painless treatment rather than an ablative or cutting application.

The benefit of the present invention of the use of the optical fiber is noted as “to radiate the wound’s surface from a distance of several millimeters. The fibers and/or the radiation spot may be manually moved over the surface of the wound or a scanner may be employed to evenly irradiate the wound site.” Further, the optical fiber may be in very close proximity to the wound to increase the power density and limit the area of application. Page 7, lines 19 to 26. This is clearly different than the use of tanning lamps, which broadly emit their rays and, while Wolff has attempted to keep them modest in size, they are not designed to apply power densities accurately.

The combination of finding that power densities, W/cm^2 , and wavelengths where hydrated tissue absorbs well, does provide one skilled in the art with reasons why the use of an optical fiber to deliver radiation to a treatment site would be beneficial. In the case of PhotoDynamic Therapy (PDT) as described in Whitehurst, the ability to ‘focus’ the emitted radiation on areas where the photosensitizer was present helped the process. However, his ‘focus’ of 6 mm or less diameter (col. 2, line 7) is less than used within the context of the present invention (see e.g. example 1 page 7).

Likewise the Examiner states as to claim 2, “the power density of the Wolff device to be at least $1 \text{ W}/\text{cm}^2$...” A review of this patent found no such device, the examples are all in the range of $10 \text{ mW}/\text{cm}^2$, that is over two orders of magnitude lower than the present invention. This is very significantly different, namely two orders of magnitude smaller than the present invention. When dealing with body tissue or any organic-based material no doctor or researcher would think such an increase in power density was automatically fine when a non-ablating radiation is required/desired.

Neither Wolff nor Whitehurst fully teach or imply the results and specifics described and claimed in the present invention, without the examiner extrapolating greatly from the material of these two patents. As a scientific worker within the field of optical fibers and lasers, being sold into the medical field for the past 27 years, I find the examiner’s after the fact extrapolations from unwritten material within the respective references makes ‘extraneous’

much of the experimentation and research done over the period before and after the present invention was filed.

This was also noted earlier on page 6 of the prior reply. The features of the present invention are not mere design choices and are not obvious in light of an artisan, at the time of filing, who was looking to direct the radiation. These are significantly different parameter ranges, well beyond simple trial and error minor experimentation.

Further the examiner's blanket comment "concerning the use of radiation with a wavelength of 930 (sic 980), those of ordinary skill in the art would have considered the exact wavelength of operation to be an application dependent parameter" either means he does not understand that the wavelength of a laser is not variable, or totally has not looked at the state of the art on spectroscopic knowledge available to practitioners at the time of submission of the present invention. It has a strong character of sounding cavalier.

Apparently as to the wavelength range of about 980 nm, mentioned above and in the examples of specification, the examiner has continued to misread 980 nm as 930 nm for some unknown reason. The value or surprise of this wavelength functioning well in the treatment of Stage 1 and Stage 2 wounds is dependent on speaking about the correct wavelength, which has known properties which are somewhat unique when dealing with body tissue, i.e. material primarily composed of water. From spectroscopy, the wavelength was known to be much more absorbed by water-based materials for good or bad. In many hair removal laser applications this was found to be potentially dangerous feature due to ease of causing harm to the skin during treatment. As noted earlier within the assignee and other optics based medical device researchers/developers, this wavelength was shown to be near ideal for cutting or cauterizing soft body tissue, such as skin, gums in the oral cavity, etc. See e.g. US 5,496,308, 5,647,867, 6,383,179, or 6,165,205.

The applicant notes that on page 3, lines 9 to 13, "it has been shown that irradiation of an open wound with a 980 nm laser at powers of at least 5 Watts, continuously applied for a period between 10 seconds and 20 minutes or greater, is an effective method of stimulating the healing of open wounds." Reference is made to U.S. Patent 6,165,205, being assigned to present assignee, and thus shows the state of the art as applied to the present invention by the inventor who works for the assignee.

The examples shown in the present application specifically disclose the use of 980 nm laser radiation applied by optical fiber and having a power density of about 5 to 45 W/cm².

It therefore can be asserted that the specification does identify 980 nm and neither Wolff nor Whitehurst make obvious the present invention, because of significantly different levels of power density employed and type of light energy as well.

Further, U.S. Patent 6,165,205, being assigned to the present assignee, is directed at the treatment of wounds that have progressed beyond the Stage 2 to open wounds; for example, where there is a need for production of fibroblasts, synthesis of collagen and removal of dead tissue and fibrin. These aspects are significantly different as to kind rather than just degree of the aspects to be solved by the current invention. Note also as noted earlier the common ownership of the present invention and the patent.

With these changes and remarks, it is believed that the disclosure is now in condition for allowance and reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

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Respectfully submitted,



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